K121098

510(k) Summary

JAN 17 2013

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 11/09/2012

1. Submitter

	Submitter
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2. U.S Agent/Contact Person

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3. Device

Trade Name: Hero I Dental Implant System
Common Name: Dental Implant
Classification Name: Endosseous Dental Implant System
Product Code: DZE, NHA
Classification regulation: 21CFR872.3640

2. Predicate Device:

RENOVA™ Internal Hex Implant System by Lifecore Biomedical, Inc. (K032774)
OsseoFuse Dental Implant System by Dynamic Innovations Inc. (K110577)
Hero II and IS Dental Implant System by KJ Meditech Co., Ltd. (K121047)

3. Description:

The Hero I Dental Implant System is made of Titanium 6AL 4V ELI alloy intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. The implant may be used to replace one or more missing teeth. The system is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition an performance characteristics. The surface of the system has been treated with R.B.M (Resorbable Blast Media).

4. Indication for use:

The Hero I is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Hero I Dental Implant System is for single and two stage surgical procedures. The system is intended for delayed loading.

5. Basis for Substantial Equivalence

The Hero I Dental Implant system has the same intended use as the identified predicate devices. The Hero I is similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium with RBM roughened surfaces. They all share same internal hexagon abutment connection system with internal beveled interface for maximum prosthetic stability. The subject and the predicate devices are bone-level implants that share similar body shape design such as straight walled neck and tapered body design.

The subject and the predicate devices are similar in size, materials, surface treatment, and are sterilization method. When compared with the predicate devices, no new question of safety or effectiveness has been raised for the Hero I Dental Implant System.

6. Conclusion

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and the predicate implant are all made of commercially pure titanium and have the same surface treatment.
Overall, the Hero I Dental Implant system has the following similarities to the predicate devices:
* has the same intended use,
* uses the same operating principle,
* incorporates the same basic design,
* incorporates the same material and the surface treatment.

Based on the similarities, we conclude that the Hero I Dental Implant system is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 17, 2013

KJ Meditech Company
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group
951 Starbuck Street
Unit J
FULLERTON CA 92833

Re: K121098
Trade/Device Name: Hero I Dental Implant System
Regulation Number: 12 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 21, 2012
Received: December 26, 2012

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121098

Device Name: Hero I Dental Implant System

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Prescription Use __√__ **AND** **Over-The Counter Use**_____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.14 11:51:34 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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